

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF NEW YORK**

UNITED STATES OF AMERICA; the States of CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, WASHINGTON and WISCONSIN; the DISTRICT OF COLUMBIA, THE CITY OF CHICAGO and THE CITY OF NEW YORK; ex rel., STEVEN M. CAMBURN

No. 13 Civ. 3700 (KMW)

STIPULATED PROTECTIVE ORDER FOR PRODUCTION BY NON-PARTY, THE CENTERS FOR MEDICARE & MEDICAID SERVICES

Plaintiff and Relator,

vs.

NOVARTIS PHARMACEUTICALS CORPORATION,

Defendant.

**THE HONORABLE GABRIEL W. GORENSTEIN, UNITED STATES MAGISTRATE JUDGE:**

WHEREAS, the Parties to this action request that this Court issue a protective order (the “Protective Order”) pursuant to Federal Rule of Civil Procedure 26(c) to protect the production by non-party the Centers for Medicare & Medicaid Services (“CMS”) to preserve the confidentiality of Protected Health Information (PHI) and financial, commercial, and trade secret information that may be produced in discovery in this action. The Parties agree that a protective order concerning such information is necessary to protect the confidentiality and integrity of the information, and to prevent injury (including without limitation financial and competitive injury) that the Producing Party or the person who is the subject of the information might incur from public disclosure. The Parties have agreed to the following terms of confidentiality, and the court has found that good

cause exists for issuance of an appropriately-tailored Protective Order governing all phases of this action. It is therefore ORDERED:

1. **Definitions.** As used in this Protective Order,

- (a) “Commercially Sensitive Information” means information that the Producing Party believes would result in competitive, commercial, or financial harm, including pricing information, reimbursement rates, rebate terms, minimum guarantee payments, sales reports, sales margins, and contracts or agreements between pharmaceutical companies and pharmacy benefit managers.
- (b) “Conclusion” means the end time for any records retention requirement and statute of limitations applicable to a party or a party’s counsel.
- (c) “Covered Entity or Entities” means “covered entity” as defined in 45 C.F.R. § 160.103.
- (d) “Discovery Material” is intended to be comprehensive and includes any and all CMS produced materials, including documents, information, electronically-stored information (ESI) and tangible things in the broadest sense contemplated under Federal Rules of Civil Procedure 34, and includes all written, oral, recorded, electronic, or graphic material, however produced or reproduced, including, but not limited to all written or printed matter of any kind, computer data of any kind, graphic or manual records or representations of any kind, and electronic, mechanical, or electric records furnished in the course of discovery under this Protective Order by the signatories to this Protective Order, and other persons or entities subject to this Protective Order, including deposition testimony and exhibits, answers to interrogatories, and responses to discovery requests and subpoenas issued under this Protective Order.

- (e) "Litigation" means the above-captioned case as well as all related appellate proceedings.
- (f) "Parties" means any plaintiff and defendant in this action.
- (g) "Producing Party" means CMS or any CMS contractor or CMS agent that produces Discovery Material pursuant to this Protective Order.
- (h) "Proprietary Information" means trade secret or other confidential research, development, or commercial information entitled to protection under Federal Rules of Civil Procedure 26(c)(1)(G).
- (i) "Protected Health Information" or "PHI" means "protected health information" as defined in 45 C.F.R. § 160.103.
- (j) "Service Providers" means any court reporter service, videographer service, translation service, photocopy service, document management service, records management service, graphics service, or other such litigation service designated by a party or a party's legal counsel in this case.

**2. CONFIDENTIAL Information.** Information designated as "CONFIDENTIAL" pursuant to this Protective Order (hereinafter "CONFIDENTIAL Information") means Discovery Material that contains PHI and any Discovery Material that would be protected by the Privacy Act of 1974, 5 U.S.C. § 552a, and/or 45 C.F.R. Part 5b in the hands of CMS.

**3. HIGHLY CONFIDENTIAL Information.** Information designated as "HIGHLY CONFIDENTIAL" pursuant to this Protective Order (hereinafter "HIGHLY CONFIDENTIAL Information") means Discovery Material that contains Proprietary Information or Commercially Sensitive Information.

**4. Designation of Material as CONFIDENTIAL.** Upon producing Discovery Material to the Parties pursuant to a subpoena or other lawful process, the Producing Party should designate the Discovery Material as “CONFIDENTIAL.” The Producing Party shall, if practical, designate “CONFIDENTIAL” on every page of the Discovery Material in the same manner in which every page is Bates stamped. If it is not practical to designate “CONFIDENTIAL” on the Discovery Material, then the Producing Party shall designate the Discovery Material as “CONFIDENTIAL” in correspondence or in some other manner reasonably giving notice of the designation, including (but not limited to) affixing a label marked “CONFIDENTIAL” on the cover of or surface of any electronic media. It is practical to designate “CONFIDENTIAL” on every page of the Discovery Material if it is produced with a Bates stamp on every page. It is not practical to designate “CONFIDENTIAL” on every page of the Discovery Material if it is a spreadsheet or presentation file produced in native format (*e.g.*, Microsoft Excel, PowerPoint, or Access).

**5. Designation of Material as HIGHLY CONFIDENTIAL.** Upon producing Discovery Material containing Proprietary Information or Commercially Sensitive Information to the Parties pursuant to a subpoena or other lawful process, the Producing Party should designate the Discovery Material as “HIGHLY CONFIDENTIAL.” The Producing Party shall, if practical, designate “HIGHLY CONFIDENTIAL” on every page of the Discovery Material in the same manner in which every page is Bates stamped. If it is not practical to designate “HIGHLY CONFIDENTIAL” on the Discovery Material, then the Producing Party shall designate the Discovery Material as “HIGHLY CONFIDENTIAL” in correspondence or in some other manner reasonably giving notice of the designation, including (but not limited to) affixing a label marked “HIGHLY CONFIDENTIAL” on the cover of or surface of any electronic media. It is practical to designate “HIGHLY CONFIDENTIAL” on every page of the Discovery Material if it is

produced with a Bates stamp on every page. It is not practical to designate “HIGHLY CONFIDENTIAL” on every page of the Discovery Material if it is a spreadsheet or presentation file produced in native format (*e.g.*, Microsoft Excel, PowerPoint, or Access).

**6. Access to CONFIDENTIAL Information.** As needed to pursue the Litigation, and subject to paragraph 8, the Parties shall permit only the following persons to have access to CONFIDENTIAL Information:

- (a) The Parties’ outside legal counsel and their employees and agents;
- (b) The Parties’ in-house legal counsel, employees, and agents;
- (c) Any Service Providers;
- (d) The Parties’ experts and consultants and their employees and agents;
- (e) Individuals who any party or party’s legal counsel interviews or deposes;
- (f) The court and court-related personnel; and
- (g) Such other persons if this court so orders.

**7. Access to HIGHLY CONFIDENTIAL Information.** As needed to pursue the Litigation, and subject to paragraph 8, the Parties shall permit only the following persons to have access to HIGHLY CONFIDENTIAL Information:

- (a) The Parties’ outside legal counsel, and outside legal counsel’s employees and agents;
- (b) The Parties’ in-house legal counsel, and in-house legal counsel’s employees and agents;
- (c) Any Service Providers;
- (d) The Parties’ experts and consultants and their employees and agents;
- (e) Individuals who any party or party’s legal counsel interviews or deposes;
- (f) The court and court-related personnel; and

(g) Such other persons if this court so orders.

**8. Acknowledgment of Protective Order by Designated Individuals.** Except for the individuals designated under paragraphs 6(f) and 7(f), the Parties shall ensure that each individual designated in paragraphs 6 and 7 who reviews or is given access to Discovery Materials reads, agrees to, and signs a copy of the attached Acknowledgement of Protective Order, except that entry of this Protective Order by the court will constitute Acknowledgement by the Parties and their legal counsel. Where an entity is designated in paragraphs 6 and 7, an officer or manager of the entity may sign the Acknowledgement of Protective Order on behalf of the entire entity. Each party's legal counsel shall maintain the copy of the Acknowledgement of Protective Order as signed by each individual or entity designated in paragraphs 6 and 7 and shall permit the opposing party's legal counsel and U.S. Department of Health and Human Services (HHS) Office of the General Counsel, CMS Division to inspect said copy or copies upon request. Individuals and entities designated in paragraphs 6 and 7, except for the individuals designated under paragraphs 6(f) and 7(f), who do not sign the attached Acknowledgement of Protective Order must not be given access to Discovery Materials.

**9. Destruction of CONFIDENTIAL Information and HIGHLY CONFIDENTIAL Information at the Conclusion of the Litigation.** No later than 90 days following the Conclusion of the Litigation, the Parties and the individuals and entities designated in paragraphs 6 and 7 shall destroy all CONFIDENTIAL Information and HIGHLY CONFIDENTIAL Information (including all copies made).

All counsel of record shall certify compliance with paragraph 9 on behalf of themselves, the Parties they represent, and the Parties' employees and agents (including, but not limited to, the individuals and entities designated in paragraphs 6 and 7, as applicable) and shall deliver this

certification to HHS Office of the General Counsel, CMS Division not more than 90 days after the Conclusion of the Litigation.

**10. Use of CONFIDENTIAL Information or HIGHLY CONFIDENTIAL Information in documents filed with the court.** In the event any party wishes to use CONFIDENTIAL Information or HIGHLY CONFIDENTIAL Information in any affidavits, briefs, memoranda, exhibits, motions, or other papers filed in court in this action, such party shall take appropriate steps to safeguard CONFIDENTIAL Information or HIGHLY CONFIDENTIAL Information, including ensuring compliance with all applicable local rules and district court rules. Where the papers to be filed contain CONFIDENTIAL Information or HIGHLY CONFIDENTIAL Information not pertinent to the issue before the court, the Parties should redact such CONFIDENTIAL Information or HIGHLY CONFIDENTIAL Information. Where the filing party wishes the court to review the CONFIDENTIAL Information or HIGHLY CONFIDENTIAL Information filed with the court, and all portions of pleadings, motions or other papers filed with the court that disclose such CONFIDENTIAL Information or HIGHLY CONFIDENTIAL Information, the filing party must make the filing under seal with the clerk of the court and the filing should remain under seal until further order of the court. The Parties will use their best efforts to minimize such sealing.

**Paragraphs 11-14 - Terms Specific to PHI.**

11. Pursuant to 45 C.F.R. § 164.512(e)(1) and for purposes of compliance with the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), the Parties’ legal counsel in this case, the employees and agents of each party, and all non-party Covered Entities are expressly and specifically authorized to use or disclose PHI in accordance with this order to:

- (a) Respond to interrogatories, requests for admission, or requests for production of documents, including ESI, served pursuant to the Federal Rules of Civil Procedure in this case seeking PHI;
- (b) Request interviews or depositions and interview, depose, or respond in interviews or depositions in which PHI might be disclosed;
- (c) Prepare briefs and other materials for the court so long as such materials are treated in accordance with paragraph 10 of this Protective Order; and
- (d) Disclose PHI to a party's experts, consultants and their employees and agents, regardless of whether the expert is a consulting or testifying expert.

12. Pursuant to 45 C.F.R. § 164.512(e)(1) and for purposes of HIPAA compliance, each deponent noticed for deposition in this case, including but not limited to a party, a fact witness, a records custodian, an expert, or a Covered Entity of any type, is expressly and specifically authorized to use or to disclose to the Parties' legal counsel in this case and the employees and agents of each party and each party's legal counsel in this case, the PHI that is responsive to deposition questions or a valid subpoena *duces tecum*.

13. Pursuant to 45 C.F.R. § 164.512(e)(1) and for purposes of HIPAA compliance, any person or entity authorized or ordered under paragraphs 11 or 12 above to use or disclose PHI is expressly and specifically authorized to do so with, to, or before any Service Providers designated by a party or a party's legal counsel in this case. The protections and requirements of paragraphs 16 and 19 of this Protective Order must be imposed on Service Providers as a condition of any Service Provider's receipt of PHI. Each party or the party's legal counsel is charged with obtaining advance consent of such Service Provider to comply with this paragraph. Upon such consent, the Service Provider will be deemed to have voluntarily submitted to this court's jurisdiction during

the pendency of this case for purposes of enforcement of this paragraph, including but not limited to the imposition of such sanctions as may be appropriate for any non-compliance.

14. The intent of this Protective Order is to authorize the use and disclosure of PHI in accordance with 45 C.F.R. § 164.512(e) and the terms of this Protective Order. To the extent that the uses and disclosures of PHI authorized under this Protective Order may be permitted under other provisions of the HIPAA Privacy Rule, such uses and disclosures are made pursuant to and in accordance with 45 C.F.R. § 164.512(e). This paragraph does not apply to uses and disclosures of PHI that are not authorized under this Protective Order.

**15. Terms Specific to Proprietary Information and Commercially Sensitive Information.** For Discovery Materials containing Proprietary Information or Commercially Sensitive Information designated as HIGHLY CONFIDENTIAL, the Producing Party's production of HIGHLY CONFIDENTIAL Information in this case is not to be construed as waiving or diminishing the Producing Party's interests in and rights to the confidentiality of Proprietary Information or Commercially Sensitive Information, unless otherwise ordered by the court.

16. Discovery Material may not be disclosed or used by any party or any individual or entity designated in paragraphs 6 or 7 for any purpose other than the Litigation.

17. Subject to paragraph 19, all CONFIDENTIAL Information and HIGHLY CONFIDENTIAL Information produced, transmitted, or otherwise received electronically must be maintained in a reasonably secure manner and guarded against re-disclosure for the life of the record.

**18. Inadvertent production by the Producing Party.** If at any time prior to the trial of this action, the Producing Party realizes that:

- (a) Some portion(s) of Discovery Material was produced without a designation of CONFIDENTIAL or HIGHLY CONFIDENTIAL, the Producing Party may add either designation to those Discovery Materials without limitation by apprising the Parties in writing of such designation. Such Discovery Material will thereafter be treated as CONFIDENTIAL Information or HIGHLY CONFIDENTIAL Information under the terms of this Protective Order. Any failure of the Producing Party to designate Discovery Material as CONFIDENTIAL or HIGHLY CONFIDENTIAL does not constitute a waiver of any claim of privilege or work product protection with respect to the Discovery Material.
- (b) If Discovery Materials subject to a claim of attorney-client privilege or attorney work product protection (“Inadvertently Disclosed Information”) were inadvertently produced, the Producing Party will be entitled to “clawback” this Inadvertently Disclosed Information and to have all copies of it either returned to the Producing Party or destroyed. If the Producing Party seeks to clawback Inadvertently Disclosed Information, it is entitled to do so, regardless of the Producing Party’s diligence in initially attempting to prevent such an inadvertent disclosure. To the extent possible, the Producing Party will clawback only the portions of Discovery Materials containing information subject to a claim of attorney-client privilege or attorney work product protection. Any Inadvertent Disclosure by the Producing Party does not constitute and may not be deemed a waiver or forfeiture of any claim of privilege or work product protection with respect to the Inadvertently Disclosed Information itself and/or its subject matter with respect to this Litigation or in any other federal, state, or local proceeding, regardless of the Producing Party’s diligence in initially attempting to

prevent such disclosure. If the Producing Party makes a claim of inadvertent disclosure, the Parties shall, within five business days, return or destroy all copies of the Inadvertently Disclosed Information, and provide a certification of counsel that all such information has been returned or destroyed. Within five business days of the notification that such Inadvertently Disclosed Information has been returned or destroyed, the Producing Party shall produce a privilege log with respect to the Inadvertently Disclosed Information. The Parties may move the court for an order compelling production of the Inadvertently Disclosed Information. The motion must be filed under seal, and may not assert as a ground for entering such an order the fact or circumstances of the inadvertent production. The Producing Party retains the burden of establishing the privileged or protected nature of any Inadvertently Disclosed Information contained in Discovery Materials. Nothing in this Protective Order limits the right of any party to request an in camera review of the Inadvertently Disclosed Information.

**19. Inadvertent production or re-disclosure by a party or an individual or entity designated in paragraphs 6 or 7.** If a party or an individual or entity designated in paragraphs 6 or 7 (the “Responsible Party”) produces or discloses Discovery Material designated as CONFIDENTIAL Information or HIGHLY CONFIDENTIAL Information to a person or entity not authorized to receive such disclosure under this Protective Order, such Responsible Party shall, upon becoming aware of such disclosure, immediately inform the Producing Party. The Responsible Party also shall take all reasonable measures to cure the improper disclosure and to promptly ensure that no further or greater

Unauthorized disclosure of the Discovery Material designated as CONFIDENTIAL Information or HIGHLY CONFIDENTIAL Information.

#### **Miscellaneous Provisions**

20. Any and all Medicare Part D Prescription Drug Event (PDE) data and/or MAX data produced by the Producing Party in this action is considered CONFIDENTIAL Information and/or HIGHLY CONFIDENTIAL Information (depending on which data fields are included or excluded) as that term is used throughout this Protective Order.

21. Pursuant to 5 U.S.C. § 552a(b)(11), this Protective Order authorizes CMS to release Privacy Act-protected information covered by this Protective Order, without the consent of the subject individual.

22. The production of any Discovery Material by CMS in the course of this action, pursuant to and in compliance with the terms of this Protective Order, which might otherwise be prohibited by the Trade Secrets Act, 18 U.S.C. § 1905, constitutes a disclosure “authorized by law” under the terms of the Act.

23. Should any party bound by this Protective Order receive a subpoena, civil investigative demand, or other process from a third party seeking, requesting, or requiring disclosure of Discovery Materials produced in this Litigation designated as CONFIDENTIAL Information or HIGHLY CONFIDENTIAL Information, such person shall give notice to HHS Office of the General Counsel, CMS Division so that CMS may seek appropriate relief, if any. Notice must be made by the sooner date of ten days from the date the party received the request for production or seven days prior to the deadline for responding to the request for production, and must be in writing.

24. Notwithstanding any provisions of this Protective Order to the contrary, in accordance with any applicable federal, state, or local laws that afford heightened protection to certain categories of confidential health information, including but not limited to, records or diagnosis or treatment for alcohol or substance abuse, certain sexually transmitted diseases such as HIV/AIDS, mental health, and research pertaining to genetic testing, the party in receipt of such information shall comply with the applicable federal, state, or local law that affords heightened protection to such information.

25. Nothing in this Protective Order affects the rights of the Parties, Producing Party, or third-parties to object to discovery on grounds other than those related to the protection of CONFIDENTIAL Information or HIGHLY CONFIDENTIAL Information, nor does it preclude any party or third-party from seeking further relief or protective orders from this court as may be appropriate under the Federal Rules of Civil Procedure.

26. Any person requiring further protection of CONFIDENTIAL Information or HIGHLY CONFIDENTIAL Information may petition this court for a separate order governing the disclosure of its information.

27. The provisions of this Protective Order survive the Conclusion of this Litigation.

28. This court retains jurisdiction over all persons subject to this Protective Order to the extent necessary to enforce any obligations arising hereunder or to impose sanctions for any contempt therefore.

29. This Protective Order does not dictate the use of CONFIDENTIAL Information or HIGHLY CONFIDENTIAL designated information by a party at trial. Such use must be determined by appropriate order of the court upon noticed motion.

30. To the extent that inconsistencies exist between this Protective Order and any CMS Data Use Agreement executed by the party in receipt of applicable Discovery Materials, the provisions of this Protective Order control.

31. This Protective Order may be amended for good cause shown.

32. This Protective Order for Production by non-party CMS is intended solely to supplement the existing Protective Order in the case. It governs only Discovery Materials produced by the Producing Party as defined in this Protective Order.

SO STIPULATED AND AGREED.

/s/ Laurie Rubinow

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*Attorneys for Plaintiff-Relator*

*Attorneys for Novartis  
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SO ORDERED this 4th day of August, 2021.



The Honorable Gabriel W. Gorenstein  
United States Magistrate Judge

**EXHIBIT A: ACKNOWLEDGEMENT OF PROTECTIVE ORDER**

I, \_\_\_\_\_, [in my individual capacity] OR [as \_\_\_\_\_ (title) of \_\_\_\_\_ (entity name), on behalf of \_\_\_\_\_ (entity name)], acknowledge that I have read, understand and agree to be bound by the Stipulated Protective Order for Production by non-party the Centers for Medicare & Medicaid Services (CMS) (the “Protective Order”) in this action governing the non-disclosure of those portions of Discovery Material that have been designated as CONFIDENTIAL Information and/or HIGHLY CONFIDENTIAL Information. I agree that I will disclose such CONFIDENTIAL Information or HIGHLY CONFIDENTIAL Information only as expressly permitted by this Protective Order and only for purposes of the Litigation (as defined in the Protective Order), that I will not use, or cause to be used, the CONFIDENTIAL Information or HIGHLY CONFIDENTIAL Information for the commercial or competitive benefit of any party or competitor to any party in this Litigation, and that I will take all reasonable measures to protect the confidentiality of all such Discovery Material. No later than 90 days following the Conclusion of the Litigation, I will destroy or return to HHS Office of the General Counsel, CMS Division all CONFIDENTIAL Information and HIGHLY CONFIDENTIAL Information in my possession (including all copies made). If I am counsel of record in the Litigation, I will certify compliance with paragraph 9 of the Protective Order and deliver this certification to HHS Office of the General Counsel, CMS Division not more than 90 days after the Conclusion of the Litigation.

By acknowledging these obligations under the Protective Order, I understand that I am submitting myself to the jurisdiction of the United States District Court for the Southern District of New York for the purpose of any issue or dispute arising hereunder and that my willful violation of any term of the Protective Order could subject me to punishment for contempt of court.

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Date

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Name